K070463

Section 5
REVERA™ Wound Care 510(k)

MAY – 7 2008

510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**
   Revalesio Corporation
   5102 20th St. East
   Building 100
   Tacoma
   Washington 98424

2. **Submitter's telephone number and fax number:**
   Tel: 253 922 2600 Ext. 221
   Fax: 253 922 6247

3. **Contact person:**
   Greg J. Archambeau - Vice President of Operations and Manufacturing

4. **Date this 510(k) summary prepared:**
   February 14, 2007

5. **Trade/proprietary name of the device:**
   REVERA™ Wound Care

6. **Classification name and number of the device:**
   Liquid Bandage - 21CFR 880.5090

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   a) Oculus Innovative Sciences, Inc. "Dermacyn™ Wound Cleanser"
   FDA 510(k) No. K042729
   Clearance to market this device given by FDA on May 17, 2005
   FDA Device Classification: Class 1
   FDA Regulation Number: 21CFR 880.5090
   FDA Product Code: KMF

   b) Oculus Innovative Sciences, Inc. "Dermacyn™ Wound Dressing"
   FDA 510(k) No. K041161
   Clearance to market this device given by FDA on May 3, 2005
   FDA Device Classification: Unclassified
   FDA Regulation Number: Unclassified
   FDA Product Code: MUG

8. **Description of the device that is the subject of this premarket notification:**
   REVERA™ Wound Care, is a single use saline topical wound wash, that will be supplied in a 60 ml (2 oz) pouch. The mechanical action of the solution moving across the wound aids in the removal of foreign objects e.g. dirt and debris. No preservatives or stabilizers are added. REVERA™ Wound Care passes the USP <71> sterility test.

REVERA™ Wound Care is a prescription device intended for application by medical professionals and will not be available as an over the counter product.

9. Intended use and indication for use:

REVERA™ Wound Care is indicated for moistening and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin, in addition to moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, abrasions, and minor burns.

The intended use and indications for use apply equally to the corresponding predicate devices listed above in Section 7.

10. Technological characteristics:

REVERA™ Wound Care is a saline wound wash, as are the predicate devices.

REVERA™ Wound Care and the predicates are all prescription devices intended for application by medical professionals, and are not available as over the counter (OTC) products.

From the above information it is concluded that REVERA™ Wound Care is substantially equivalent to the above, 7a and 7b, corresponding predicate devices.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2008

Revalesio Corporation
% Mr. Greg J. Archambeau
VP of Operations and Manufacturing
5102 20th Street East
Tacoma, Washington 98424

Re: K070463
Trade/Device Name: REVERA™ Wound Care
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 16, 2008
Received: April 17, 2008

Dear Mr. Archambeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 4-1
REVERA™ Wound Care 510(k)

Indications for Use

510(k) number (if known):
Unknown - not yet assigned by FDA.

Device name:
REVERA™ Wound Care

Indications for use:
REVERA™ Wound Care is indicated for moistening and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin, in addition to moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, abrasions and minor burns.

REVERA™ Wound Care is a prescription device and the labeling indicates this.

Prescription Use ___Yes___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___No___ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K07463